EPA Reviewer: Abdallah Khasawinah, Ph.D. **Signature:** A. Khasawinah
Reregistration Branch 4, Health Effects Division (7509P) **Date** Sept. 10, 2007
EPA Secondary Reviewer: Marquea King, Ph.D. **Signature:** Marquea King
Reregistration Branch 4, Health Effects Division (7509P) **Date** 9-10-07

Template version 11/01

TXR#: 0054680

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rabbit; OPPTS 870.1200 [§81-2]; OECD 402.

PC CODE: *056704* **DP BARCODE:** D341248

TEST MATERIAL (PURITY): F&B Rabbit and Dog Chaser (mixture of tobacco, naphthalene and sterilized cattle blood)

SYNONYMS:

CITATION: Kuhn, J. (1992) Acute Dermal Toxicity Study in Rabbits: F&B Rabbit & Dog Chaser: Lab Project Number: 9643-92. Stillmeadow, Inc. MRID 42631101. Unpublished. 11 p.

SPONSOR: Faesy & Besthoff, Inc., 143 River Road, Edgewater, NJ

EXECUTIVE SUMMARY - In an acute dermal toxicity study (MRID 42631101), New Zealand White rabbits 5/sex were dermally exposed to 2020 mg of F&B Rabbit and Dog Chaser/kg body weight. Each dose was moistened with 2.22 mL of deionized water/kg body weight and was applied evenly to the hair-clipped area on the dorsal surface of the trunk area and was held for 24 hours. Animals were observed for mortality, clinical signs of toxicity, and dermal lesions for up to 14 days post-dosing.

Dermal LD_{50} is greater than 2020 mg/kg (limit dose) in males and females

F&B Rabbit and Dog Chaser is considered to be of **LOW TOXICITY** and is classified as **TOXICITY CATEGORY IV** based on the dermal LD_{50} in the females. No mortality was observed at this limit dose. Diarrhea and decreased defecation were observed mostly in males during the first 4 days. All animals gained weight. Gross necropsy conducted on each animal at the end of study (Day 14) revealed no observable abnormalities.

This study is classified **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.1200; OECD 402) for an acute dermal toxicity study in the rabbit.

COMPLIANCE - Signed and dated Data Confidentiality, GLP Compliance, and Quality Assurance statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: F&B Rabbit & Dog Chaser

Description: *Mixture of tobacco, naphthalene and sterilized cattle blood*
Batch/Lot #: Not reported
Purity (w/w): Not reported
CAS # of TGAI:

2. Vehicle control - deionized water

3. Test animals

Species: Rabbit
Strain: New Zealand White
Age/mean weight at dosing: Age 3- 6months / 2.400-2.775 kg males and 2.500-2.775 kg females
Source: Ray Nichols Rabbitry, Lumberton, Texas
Housing: Suspended, wire bottom, stainless steel; one per cage
Diet: Purina rabbit Chow; presented in measured amounts
Water: Tap water, *ad libitum*
Environmental Conditions
Temperature: Not reported
Humidity: Not reported
Air changes: Not reported
Photoperiod: Not reported
Acclimation period: At least 5 days

B. STUDY DESIGN and METHODS

1. In-life dates - Start: 12/03/1992 End: 12/17/1992

2. Animal assignment, dose rationale, and treatment – This study was a limit test that used 5 rabbits of each sex. Each animal was prepared on the day prior to treatment by clipping at least 10% of the total body surface area on the dorsal trunk area without abrading the skin. All animals were treated with 2020 mg of the test material/kg body weight. Each dose was moistened with 2.22 mL of deionized water/kg body weight and was applied evenly over the exposed area. The test material was held in contact with the skin with surgical gauze (10 x 10 cm and two layers thick). The gauze was held in place by a non-irritating adhesive tape. The entire trunk area was wrapped with a semi-permeable dressing to prevent possible ingestion of the test material. The wrappings were secured in place with non-irritating adhesive tape. After 24 hours, the wrappings were removed and the exposed area gently washed with room temperature tap water and cleaned with wet cloth to remove residual test material. Observations

were made for toxicity and mortality at ½, 3, and 6 hours after treatment and at least once daily for 14 days. Individual body weights were recorded. A gross necropsy was conducted on each animal at study termination on Day 14.

3. **Statistics** – There was no need for statistical analysis.

II. RESULTS AND DISCUSSION

A. **MORTALITY** – None of the test animals died during the 14 – day observation period.

The dermal LD_{50} of F&B Rabbit & Dog Chaser was greater than 2020 mg/kg for males and females.

B. **CLINICAL OBSERVATIONS** – **Diarrhea** and decreased defecation were observed mostly in males during the first 4 days and were no longer evident by day 13.

C. **BODY WEIGHT** - All treated groups gained weight during the study.

D. **NECROPSY** - Gross necropsy conducted on each animal at the end of study (Day 14) revealed no observable abnormalities.

E. **REVIEWER'S CONCLUSIONS** – F&B Rabbit & Dog Chaser produced minimal dermal toxicity with an LD_{50} greater than 2020 mg/kg for male and female rabbits. This study is classified **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.1200; OECD 402) for an acute dermal toxicity study in the rabbit.

F. **DEFICIENCIES** - The following deficiency was noted, but does not change the conclusions of this review:

- The environmental test conditions were not reported.

EPA Reviewer: Abdallah Khasawinah, Ph.D. **Signature:** A. Khasawinah
Reregistration Branch 4, Health Effects Division (7509P) **Date** Sept. 10, 2007
EPA Secondary Reviewer: Marquea King, Ph.D. **Signature:** M. King
Reregistration Branch 4, Health Effects Division (7509P) **Date** 9/10/07

Template version 1/01

TXR#: 0054680

DATA EVALUATION RECORD

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300 [§81-3]; OECD 403.

PC CODE: 056704 **DP BARCODE:** D341248

TEST MATERIAL (PURITY): F&B Rabbit and Dog Chaser (mixture of tobacco, naphthalene and sterilized cattle blood)

SYNONYMS:

CITATION: Holbert, M. (1992) Acute Inhalation Toxicity Study in Rats: F&B Rabbit & Dog Chaser: Lab Project Number: 9644-92. Stillmeadow, Inc. MRID 42631102. Unpublished. 17 pages.

Bennick, J. (1995) F & B Rabbit and Dog Chaser: Acute Inhalation Toxicity Study in Rats: Final Report: Lab Project Number: 2376-95: S9-FF81-3. Stillmeadow, Inc. MRID 43874001. Unpublished. 10 P.

SPONSOR: Faesy & Besthoff, Inc. 143 River Road. Edgewater, NJ

EXECUTIVE SUMMARY - In an acute inhalation toxicity study (MRID 42631102 & 43874001), young adult Sprague-Dawley rats (5/sex) were exposed by whole-body inhalation to F&B Rabbit and Dog Chaser (mixture of tobacco, naphthalene and sterilized cattle blood) for 4 hours at 5.39 mg/L aerosol of the fine powder. The animals were observed for up to 14 days post-exposure. Due to the nature of the test material, an acceptable percentage of particles less than 1 micron was not attainable, only 4.42% of the particles were under 1 micron. Attempts to aerosolize F&B Rabbit and Dog Chaser to acceptable concentrations of at least 2 mg/L and a mass median aerodynamic diameter (NMAD) between 1 and 4 microns were unsuccessful (MRID 43874001).

4-hour Inhalation LC_{50} is greater than 5.39 mg/L (limit dose) in males and females

There was no mortality during the study. F&B Rabbit and Dog Chaser is considered to be of **LOW TOXICITY** and is classified as **TOXICITY CATEGORY IV** based on the 4-hour LC_{50} in the rats. Clinical signs observed in both sexes included activity decrease, lacrimation, nasal discharge, piloerection, polyuria, respiratory gurgle and salivation. Animals were asymptomatic by Day 3. No gross lesions were observed in the animals at the terminal sacrifice. There was a treatment related decrease in body weight gain. Three females lost weight between days 0 and 7 and one female failed to gain weight

This study is classified as **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.1300; OECD 403) for an acute inhalation toxicity study in the rat.

COMPLIANCE - Signed and dated Data Confidentiality, GLP Compliance, and Quality Assurance statements were provided.

I. MATERIALS AND METHODS:

A. MATERIALS

1. Test material - F&B Rabbit & Dog Chaser

Description:	Mixture of tobacco, naphthalene and sterilized cattle blood
Lot #:	Not reported
Purity (w/w):	Not reported
CAS #:	

2. Vehicle - Air

3. Test animals

Species:	Albino Rat
Strain:	Harlan Sprague-Dawley
Age/mean weight at dosing:	Young adult/ 276-297 g males and 215 - 238 g females
Source:	Harlan Sprague-Dawley, Inc. (Houston, TX)
Housing:	Suspended, wire bottom, stainless steel (one per cage)
Diet:	Purina Formula lab Chow No. 5008, *ad libitum*; except during exposure period
Water:	Tap water, *ad libitum*, except during exposure
Environmental conditions	
Temperature:	Room temperature
Humidity:	NA
Air changes:	NA
Photoperiod:	NA
Acclimation period:	At least 5 days

B. STUDY DESIGN and METHODS

1. **In-life dates** - Start: 12/08/1992 End: 12/22/1992

2. **Exposure conditions**

a. Animal assignment and treatment – Five healthy males and five females (nulliparous and non-pregnant) were assigned to the treatment with an aerosol of the test material at 5.39 mg/L. The animals were exposed (whole body) to an aerosol generated from the test material (fine powder) for a period of 4 hours. During the 4-hour exposure, rats were housed individually in stainless steel cages within a 500 mL inhalation chamber. Due to test material covering the chamber window, no animals could be observed during the exposure period. All animals were examined daily during a 14-day observation period. All animals were weighed prior to exposure and on Days 7 and 14 post-exposure. At the conclusion of the observation period, all surviving animals were sacrificed (method not specified) and a gross necropsy was performed on each animal.

b. Generation of the test atmosphere/chamber description – The test material was sifted to a fine powder prior to exposure. The aerosol was generated by Venturi Aspirator which aspirated the test material from a motorized revolving disc delivery system coupled to the aspirator. The concentrated aerosol was then diluted and filtered with air drawn in to the exposure chamber. Air flow into the chamber was maintained at 13.8 air changes/hour. Temperature and humidity were recorded at 30 minute intervals (but not reported in the study report) during the exposure period.

The concentration of the test material in the exposure chamber was determined gravitmetrically twice per hour (taken from the breathing zone of the animals), and nominally at the end of the exposure. Particle size (taken from the breathing zone of the animals) was determined twice during the exposure, using an Andersen cascade impactor, at a rate of 28.3 L/minute for duration of 2 minutes. Although an exposure concentration of 5.39 mg/L was attained, due to the nature of the test material being a mixture of three raw components, only an average of 4.42% of particles was under 1 micron. Attempts to aerosolize F&B Rabbit and Dog Chaser to acceptable concentrations of at least 2 mg/L and a mass median aerodynamic diameter (NMAD) between 1 and 4 microns were unsuccessful (MRID 43874001). It was concluded that the test material F&B Rabbit and Dog Chaser cannot be aerosolized well enough to obtain an exposure concentration to determine the test material toxicity potential.

3. **Statistics** - There was no statistical evaluation of the data. Only a limit dose was used.

II. RESULTS and DISCUSSION

A. MORTALITY – No mortality among the exposed animals was reported.

The 4-hour Inhalation LC_{50} is greater than 5.39 mg/L for male and female rats

B. CLINICAL OBSERVATIONS - Clinical signs observed in both sexes included activity decrease, lacrimation, nasal discharge, piloerection, polyuria, respiratory gurgle and salivation. Animals were asymptomatic by Day 3.

C. BODY WEIGHT - There was a treatment related decrease in body weight gain. Three females lost weight between days 0 and 7 and one female failed to gain weight.

D. NECROPSY - No gross lesions were observed in the animals at the terminal sacrifice.

E. REVIEWER'S CONCLUSIONS - The reviewer agrees with the study author that inhalation exposure to F & B Rabbit and Dog Chaser produced minimal toxicity. F & B Rabbit and Dog Chaser is considered to be of **LOW TOXICITY** and is classified as **TOXICITY CATEGORY IV** based on the 4-hour LC_{50} in both sexes.

This study is classified as **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.1300; OECD 403) for an acute inhalation toxicity study in the rat.

F. DEFICIENCIES - The following minor deficiencies were noted, but do not change the conclusions of this DER:

- Particle size with a minimum of 1 micron was not acceptable and it was not attainable due to the nature of the test material. Attempts to aerosolize F&B Rabbit and Dog Chaser to acceptable concentrations of at least 2 mg/L and a mass median aerodynamic diameter (NMAD) between 1 and 4 microns were unsuccessful (MRID 43874001). It was concluded that the test material F&B Rabbit and Dog Chaser cannot be aerosolized well enough to obtain an exposure concentration to determine the test material toxicity potential
- A control group was not included.

EPA Reviewer: Abdallah Khasawinah, Ph.D.
Reregistration Branch 4, Health Effects Division (7509P)
EPA Secondary Reviewer: Marquea King, Ph.D.
Reregistration Branch 4, Health Effects Division (7509P)

Signature: A. Khasawinah
Date Sept. 10, 2007
Signature: Marquea King
Date 9-10-07
Template version 11/01

TXR#: 0054680

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit; OPPTS 870.2400 [§81-4]; OECD 405.

PC CODE: 056704 **DP BARCODE:** D341248

TEST MATERIAL (PURITY): F&B Rabbit and Dog Chaser

SYNONYMS: None

CITATION: Kuhn, J. (1992) Primary Eye Irritation Study in Rabbits: F&B Rabbit & Dog Chaser: Lab Project Number: 9645-92. Stillmeadow, Inc. MRID 42631103. Unpublished. 17 p.

SPONSOR: Faesy & Besthoff, Inc., 143 River Road, Edgewater, NJ

EXECUTIVE SUMMARY - In a primary eye irritation study (MRID42631103), 0.1 mL by volume (68.53 mg) of F&B Rabbit & Dog Chaser (mixture of tobacco, naphthalene and sterilized cattle blood) was instilled into the conjunctival sac of the left eye of 6 young adult (3-6 months) New Zealand White rabbits (3 males and 3 females). The lids were gently held together for 1 second. The untreated right eyes served as controls. The animals were observed for ocular lesions at 1, 24, 48, and 72 hours after treatment. All treated eyes were washed with room temperature deionized water for one minute immediately after the 24 hour observation period. Irritation was graded using modified Draize scale.

Conjunctival redness, chemosis and discharge were observed in all animals at one hour observation and cleared by 72 hours. There were no corneal or iris lesions. The maximum total irritation score was 8.7/110 at 1 hour after treatment and declined to 1.3/110 at the 48 hour observation period. Positive fluorescein staining did not occur in any eyes. Since the irritating effects were clear by 72 hours, the test material F&B Rabbit & Dog Chaser is classified as minimally irritating in **Toxicity Category III**.

This study is classified as **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.2400; OECD 405) for a primary eye irritation study in the rabbit.

COMPLIANCE - Signed and dated Data Confidentiality, GLP Compliance, and Quality Assurance statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material - F&B Rabbit & Dog Chaser

Description:	Mixture of tobacco, naphthalene and sterilized cattle blood
Lot #:	Not reported
Purity (w/w):	Not reported (certificate of analysis not provided by sponsor)
CAS #:	

2. Vehicle and/or Positive control - None

3. Test animals

Species:	Rabbit
Strain:	New Zealand White
Age/weight at dosing:	Age 3-6 months / weight not given
Source:	Ray Nichols Rabbitry, Lumberton, Texas
Housing:	Suspended, wire bottom, stainless steel; one per cage
Diet:	Purina rabbit Chow; presented in measured amounts
Water:	Tap water, *ad libitum*
Environmental conditions	
Temperature:	Not reported
Humidity:	Not reported
Air changes:	Not reported
Photoperiod:	Not reported
Acclimation period:	At least 5 days

B. STUDY DESIGN and METHODS

1. In-life dates - Start: 12/14/1992 End: 12/17/1992

2. Animal assignment and treatment - A 0.1 mL aliquot of the test material by volume (68.53 mg) was instilled into the conjunctival sac of the left eye of 6 young adult (3-6 months) New Zealand White rabbits (3 males and 3 females). The lids were gently held together for 1 second. The other eye remained untreated and served as the control. The animals were observed for ocular lesions at 1, 24, 48, and 72 hours after treatment. All treated eyes were washed with room temperature deionized water for one minute immediately after the 24 hour observation period. Irritation was graded using modified Draize scale.

II. RESULTS AND DISCUSSION

A. CLINICAL OBSERVATIONS - The incidence of 'positive' ocular irritation is presented in Table 1. Conjunctival redness, chemosis and discharge were observed in all animals at one hour observation and cleared by 72 hours. There were no corneal or iris lesions. The maximum total irritation score was 8.7/110 at 1 hour after treatment and declined to 1.3/110 at the 48 hour observation period. Positive fluorescein staining did not occur in any eyes. Since the irritating effects were clear by 48 hours, the test material F&B Rabbit & Dog Chaser is classified as minimally irritating in Toxicity Category III.

Table 1. Incidence [# affected (mean severity)] of 'positive' ocular effects in rabbits treated with F&B Rabbit and Dog Chaser. [a]

Observation	Interval (hours post-instillation)			
	1	24	48	72
Cornea	0	0)	0	0
Iris	0	0	0	0
Conjunctiva Redness	6 (2)	6 (1.6)	4 (0.6)	0
Chemosis	6 (2)	1 (0.2)	0	0
Discharge	3 (0.5)	2 (0.3)	0	0

a Data were obtained from pages15 and 16 of the study report.

B. REVIEWER'S CONCLUSIONS - F&B Rabbit and Dog Chaser is classified as **Toxicity Category IV** based on the degree of irritation which was resolved within 48 hours after treatment.

C. DEFICIENCIES - The following deficiency was noted, but does not change the conclusions of this DER:

- Test material purity (% a.i.) was not reported; however the test material was defined as a mixture of tobacco, naphthalene and sterilized cattle blood.

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EPA Reviewer: Abdallah Khasawinah, Ph.D.
Reregistration Branch 4, Health Effects Division (7509P)
EPA Secondary Reviewer: Marquea King, Ph.D.
Reregistration Branch 4, Health Effects Division (7509P)

Signature: A. Khasawinah
Date Sept. 19 200
Signature: Marquea King
Date 9-10-07

Template version 11/01

TXR: 0054680

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - (Rabbit); OPPTS 870.2500 [§81-5]: OECD 404.

PC CODE: 056704 **DP BARCODE:** D341248

TEST MATERIAL (PURITY): F&B Rabbit and Dog Chaser

SYNONYMS: None

CITATION: Kuhn, J. (1992) Primary Dermal Irritation Study in Rabbits: F&B Rabbit & Dog Chaser: Lab Project Number: 9646-92. Stillmeadow, Inc. Report no. 9646-92. MRID 42631104. Unpublished. 12 pages.

SPONSOR: Faesy & Besthoff, Inc., 143 River Road, Edgewater, NJ

EXECUTIVE SUMMARY - In a primary dermal irritation study (MRID 42631104), 3 young adult New Zealand White rabbits/sex were dermally exposed to 500 mg of F&B Rabbit & Dog Chaser (mixture of tobacco, naphthalene and sterilized cattle blood) moistened with 1.0 mL of deionized water for 4 hours. Animals were observed at 24 and 72 hours after application and on Days 4 and 7-14 for signs of erythema and edema. Skin irritation was scored using a Draize-like method (assumed by reviewers).

The only signs of dermal irritation were slight erythema in 4 of the rabbits which cleared up within 48 hours. F&B Rabbit & Dog Chaser is classified in **Toxicity Category IV** for dermal irritation.

This study is classified as **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.2500; OECD 404) for a primary dermal irritation study in the rabbit.

COMPLIANCE - Signed and dated Data Confidentiality, GLP Compliance, and Quality Assurance statements were provided.

I. MATERIALS AND METHODS:

A. MATERIALS

1. **Test material** - F&B Rabbit & Dog Chaser

Description:	Mixture of tobacco, naphthalene and sterilized cattle blood
Batch #:	Not reported
Purity (w/w):	Not reported
CAS #:	

2. **Vehicle and/or Positive control** - The test material was applied in deionized water.

3. **Test animals**

Species:	Rabbit
Strain:	New Zealand White
Age/weight at dosing:	*Age3-6 months / weight not given*
Source:	Ray Nichols Rabbitry, Lumberton, Texas
Housing:	Suspended, wire bottom, stainless steel; one per cage
Diet:	Purina rabbit Chow; presented in measured amounts
Water:	Tap water, *ad libitum*
Environmental conditions	
Temperature:	Not reported
Humidity:	Not reported
Air changes:	Not reported
Photoperiod:	Not reported
Acclimation period:	At least 5 days

B. STUDY DESIGN and METHODS

1. **In-life dates** - Start: 11/17/1992 End: 11/20/1992

2. **Animal assignment and treatment** - The hair was clipped from the dorsal area (8 x 8 cm) of the trunk of 3 male and 3 female New Zealand White rabbits. Each exposure area was large enough to include both a test site and a control area. Each test site was treated with 500 mg of the test material moistened with 1.0 mL of deionized water on a 2.5 x 2.5 cm surgical gauze patch. Each patch was secured with a strip of non-irritating adhesive tape. The entire trunk of each animal was wrapped loosely with a semi-permeable dressing to retard evaporation and to prevent possible ingestion of the test material. Four hours after treatment, the wrappings and patches were removed. The test sites were gently washed with room temperature tap water and a wet cloth to remove much of the residual test material. The test sites were examined for erythema and eschar formation, edema formation, and other dermal irritation. Observations were conducted at ¾, 24, 48 and 72 hours after washing. Skin irritation was scored using a modified Draize method.

II. RESULTS AND DISCUSSION

A. REPORTED RESULTS – The only signs of dermal irritation were slight erythema in 4 of the rabbits which cleared up within 48 hours as shown in Table 1.

Table 1. Incidence [# affected (average severity)] of dermal effects in male and female rabbits dermally exposed to 500 mg of F&B Rabbit & Dog Chaser moistened with 1.0 mL deionized water for 4 hours. [a]

Interval (post-washing)	Hair-clipped Skin	
	Erythema	Edema
¾ hours	4 (0.6)	0
24 hours	1 (0.16)	0
48 hours	1 (0.16)	0
72 hours	0	0

a Data were obtained from page 12 of the study report; Numbers presented parenthetically are the average severity (calculated by the reviewer).

B. REVIEWER'S CONCLUSIONS - The reviewers agree that F&B Rabbit & Dog Chaser is not a dermal irritant based on very slight temporary erythema in few animals that cleared within 72 hours. F&B Rabbit & Dog Chaser is classified in Toxicity Category IV for dermal irritation.

C. DEFICIENCIES - The following deficiency was noted, but does not change the conclusions of this DER:

- Test material purity (% a.i.) was not reported; however the test material was defined as a mixture of tobacco, naphthalene and sterilized cattle blood.

EPA Reviewer: Abdallah Khasawinah, Ph.D.
Reregistration Branch 4, Health Effects Division (7509P)
EPA Secondary Reviewer: Marquea King, Ph.D.
Reregistration Branch 4, Health Effects Division (7509P)

Signature: A. Khasawinah
Date Sept. 10, 2007
Signature: Dr. M. King
Date 9-10-07
Template version 02/06

TXR#: 0054680

DATA EVALUATION RECORD

STUDY TYPE: Skin Sensitization - Guinea Pig; OPPTS 870.2600 [§81-6]; OECD 406.

PC CODE: 056704 **DP BARCODE:** D341248

TEST MATERIAL (PURITY): F&B Rabbit and Dog Chaser

SYNONYMS:

CITATION: Kuhn, J. (1993) Dermal Sensitization Study in Guinea Pigs: F&B Rabbit & Dog Chaser: Lab Project Number: 9647-92. Stillmeadow, Inc. MRID 42640001. Unpublished. 17p.

Kuhn, J. (1994) Dermal Sensitization study in Guinea Pigs: F&B Rabbit & Dog Chaser: Amendment: Lab Project Number: 9647-92. Stillmeadow, Inc. MRID 43375601. Unpublished. 10 p.

SPONSOR: Faesy & Besthoff, Inc., 143 River Road, Edgewater, NJ

EXECUTIVE SUMMARY - In a dermal sensitization study (MRID 42640001), Hartley albino guinea pigs (5/sex) were exposed to F&B Rabbit & Dog Chaser using a modified Buehler method. Positive control data for dinitrochlorobenzene (DNCB) were provided in an amended MRID 43375601.

No dermal effects were observed in the treated animals during either the induction or challenge phases. In this study F&B Rabbit & Dog Chaser **is not a dermal sensitizer.**

This study is classified as **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.2600; OECD 406) for a dermal sensitization study in the guinea pig.

COMPLIANCE - Signed and dated Data Confidentiality, GLP Compliance, and Quality Assurance statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test material** - F&B Rabbit & Dog Chaser
   Description: Mixture of tobacco, naphthalene and sterilized cattle blood
   Lot/Batch #: Not reported
   Purity: Not reported
   CAS # of TGAI:

2. **Vehicle and/or positive control** - The test material was suspended in distilled water. Positive control data for 1-chloro-2,4-dinitrochlorobenzene (DNCB) were provided in MRID 43375601.

3. **Test animals**
   Species: Guinea pig
   Strain: Hartley-derived albino
   Age/weight at study initiation: Age not reported/270-340 g males; 270-310 g females
   Source: SASCO, Inc.
   Housing: 1-4 of the same sex / suspended stainless steel cage
   Diet: Purina Guinea Pig Chow; *ad libitum*
   Water: Tap water; *ad libitum*
   Environmental conditions
   Temperature: Room temperature
   Humidity: Not reported
   Air changes: Not reported
   Photoperiod: Not reported
   Acclimation period: At least 5 days

B. STUDY DESIGN

1. **In-life dates** - Start: 12/16/1992 End: 01/15/1993

2. **Animal assignment and treatment** - The Buehler method was used in this study. All animals were weighed prior to the first induction treatment and prior to challenge. Prior to the induction phase, a preliminary screening study was performed to establish the appropriate concentration of the test material for induction and challenge. In the preliminary screening test, the hair was clipped from the dorsal trunk area of 2 animals/sex. Approximately 24 hours later, tested in the screening were 400 mg of the solid test material moistened with deionized water and 75%, 50% and 25% w/v concentrations of the test material moistened with deionized water. Each concentration was first applied to a Coverlet adhesive dressing 3.8 x 5 cm patch and the patches were applied to the animals. Each animal was then placed individually in a restrainer for approximately 6 hours. The patches were secured by wrapping with clear polyethylene film. Approximately 6 hours after initiation of exposure, the dressings were removed and the animals were returned to their individual cages. Approximately 20 hours later, the test sites were evaluated for dermal irritation. The test material produced no irritation at the treatment sites. Therefore 400 mg dose of the test material was selected for the sensitization test.

In the induction phase of the sensitization study, the back of the trunk was clipped of hair from 5 animals/sex/treatment group (naïve and test groups) to expose a longitudinal area at least 8 x 10 cm on each animal. The animals were clipped again as necessary. The same treatment regimen (400 mg test material) in the screening was used for all inductions done on days 1, 8 and 15. At challenge, all animals were treated with a dose in a manner identical to the induction treatment, except the test site was laterally on the right rear quadrant of the exposure area. Observations for skin reactions at each test site were made approximately 24 hours after each treatment. In addition, observations for the skin reactions were made approximately 48 hours after the first induction treatment, and 48 hours after the challenge treatment. The scoring scale used for grading skin reactions is presented below:

0	No reaction
0.5	Very faint erythema, usually nonconfluent
1	Faint erythema, usually confluent
2	Moderate erythema
3	Severe erythema with or without edema

II. RESULTS AND DISCUSSION

A. INDUCTION REACTIONS AND DURATION – No dermal to very slight dermal irritation (scores of 0 – 0.5) was observed during the induction phase.

B. CHALLENGE REACTIONS AND DURATION - No marked dermal irritation was observed in any of the challenge sites or the treated naive animals. No treatment-related effects in body weight were observed.

C. POSITIVE CONTROL - Positive control data for dinitrochlorobenzene (DNCB) were provided in MRID 43375601. A mean score of 0.8 for the DNCB test material group after challenge, when compared with the naïve control group mean challenge score of 0.0, confirmed the sensitivity of the guinea pigs to the positive control material.

D. REVIEWER'S CONCLUSIONS - The reviewer agrees with the investigator that under the conditions of this study, F&B Rabbit and Dog Chaser is not a dermal sensitizer in guinea pigs.

E. DEFICIENCIES - The following deficiencies were noted, but do not change the conclusions of this DER:

- Test material purity (% a.i.) was not reported; however the test material was defined as a mixture of tobacco, naphthalene and sterilized cattle blood.
- Environmental conditions were not described.

EPA Reviewer: Abdallah Khasawinah, Ph.D. **Signature:** A. Khasawinah
Reregistration Branch 4, Health Effects Division (7509P) **Date** Sept. 19 2007
EPA Secondary Reviewer: Marquea King, Ph.D. **Signature:** M King
Reregistration Branch 4, Health Effects Division (7509P) **Date** 9-10-07

Template version 11/01

TXR#: 0054680

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat; OPPTS 870.1100 [§81-1]; OECD 401.

PC CODE: 056704 **DP BARCODE:** D341248

TEST MATERIAL (PURITY): F&B Rabbit and Dog Chaser (mixture of tobacco, naphthalene and sterilized cattle blood)

SYNONYMS:

CITATION: Kuhn, J. (1994) Acute Oral Toxicity Study in Rats: (F & B Rabbit and Dog Chaser): Final Report: Lab Project Number:1607-94. Stillmeadow, Inc. MRID 43523301. Unpublished. 11 pages.

SPONSOR: Faesy & Besthoff, Inc. 143 River Road. Edgewater, NJ

EXECUTIVE SUMMARY - - In an acute oral toxicity study (MRID 43523301), Sprague-Dawley albino rats, 5/sex were fasted overnight and then given single oral dose of 5050 mg/kg of F&B Rabbit and Dog Chaser. This material is a mixture of tobacco, naphthalene and sterilized cattle blood. The animals were observed for up to 14 days. The test material was given by gavage in a 30% w/v concentration in 2% w/v carboxymethyl cellulose dissolved in deionized water. Each individual animal was given a volume of 16.8 mL/kg adjusted for fasted body weight.

Oral LD_{50} is greater than 5050 mg/kg (limit dose) in males and females

F&B Rabbit and Dog Chaser is considered to be of **Low Toxicity** and is classified as **TOXICITY CATEGORY IV**. None of the animals died. Clinical signs observed in both sexes included activity decrease, diarrhea, crust around the eyes and nose, piloerection, polyuria, ptosis, respiratory gurgle and salivation. Animals were asymptomatic by Day 8. Body weight gains were not affected by the treatment. No treatment-related gross lesions were observed at necropsy.

This study is classified **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.1100; OECD 401) for an acute oral toxicity study in the rat.

COMPLIANCE - Signed and dated Data Confidentiality, GLP Compliance, and Quality Assurance statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: F&B Rabbit & Dog Chaser

Description:	Mixture of tobacco, naphthalene and sterilized cattle blood
Lot #:	Not reported
Purity (w/w):	Not reported
CAS # of TGAI:	

2. Vehicle and/or positive control - The test material was applied in deionized water in 2% w/v carboxymethyl cellulose (CMC).

3. Test animals

Species:	Albino Rat
Strain:	HSD:Sprague-Dawley
Age/mean weight at Day 1:	Young adult/261-280 g males and 208-243 g females
Source:	Harlan Sprague-Dawley, Inc. (Houston, TX)
Housing:	Suspended, wire bottom, stainless steel (one per cage)
Diet:	Purina Formula lab Chow No. 5008, *ad libitum*; except for overnight (16 hours) prior to dosing.
Water:	Tap water, *ad libitum*
Environmental Conditions	
Temperature:	72 ± 5°F
Humidity:	30-80%
Air changes:	10-12 changes/hour
Photoperiod:	12 hrs dark/12 hrs light
Acclimation period:	*At least 5 days*

B. STUDY DESIGN and METHODS

1. In-life dates - Start: 11/02/1994 End: 11/16/1994

2. Animal assignment and treatment - Animals were randomly assigned. After an overnight fast (16 hr), rats received a single gavage dose of 5050 mg/kg of F&B Rabbit and Dog Chaser (mixture of tobacco, naphthalene and sterilized cattle blood) and were observed for up to 14 days. The test material was given in a 30% w/v concentration in 2% w/v carboxymethyl cellulose at a volume of 16.8 mL/kg adjusted for body weight of the individual animals. All animals were weighed prior to dosing on Day 1 and on Days 7 and 14 (prior to necropsy). All animals were sacrificed on Day 14 by an overdose of carbon dioxide and subjected to a necropsy.

3. **Statistics** – No statistical evaluation conducted.

II. RESULTS AND DISCUSSION

A. MORTALITY – There was no mortality during the 14 day observation period among the treated animlas.

The oral LD_{50} is greater than 5050 mg/kg (limit dose) in males and females

B. CLINICAL OBSERVATIONS - Clinical signs observed in both sexes included activity decrease, diarrhea, crust around the eyes and nose, piloerection, polyuria, ptosis, respiratory gurgle and salivation. Animals were asymptomatic by Day 8.

C. BODY WEIGHT - Body weight gains were not affected by the treatment.

D. NECROPSY - No treatment-related lesions were observed in any tissues examined during necropsy. Two males had discolored lungs and a discolored thymus in one of them. These were considered to be possibly related to the administration of the test material and not to the test material itself.

E. REVIEWER'S CONCLUSIONS - The reviewer agrees with the investigators that the oral LD_{50} is greater than 5050 mg/kg (limit dose) in males and females.

This study is classified **acceptable/guideline** and satisfies the guideline requirement (OPPTS 870.1100; OECD 401) for an acute oral toxicity study in the rat.

F. DEFICIENCIES – Test material purity (% a.i.) was not reported; however the test material was defined as a mixture of tobacco, naphthalene and sterilized cattle blood.